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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/596,362	06/17/00	STEINER	G

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HM12/0501

EXAMINER

WARE, T

ART UNIT

PAPER NUMBER

1615

AIR MAIL

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/596,362

Applicant(s)

STEINER, GREGORY

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of preliminary amendment filed 3-6-01 is acknowledged. Claims 1-9 have been amended as requested.

### ***Specification***

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because it contains language referring to purported merits or speculative application of the invention and compares the invention with the prior art. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

Art Unit: 1615

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Recitation of "chemopreventing" is not enabled by the specification as prevention suggests that 100% of the craving would be blocked and it is submitted that it would be impossible to completely block the craving. "Chemo" suggests that the craving is blocked chemically. Indeed, page 8, lines 10-14 of the specification indicate that kava has an "anticraving effect by acting as an antagonist for those dopaminergic neurons responsible for acute craving and its effect on 5-HT." Unless, an antagonist binds non-competitively, the antagonist is in a state of flux between its bound (i.e. to a receptor) and unbound state. Thus, some of the antagonist will be bound to the site of action and some will not. Likewise, some of the sites of action will be bound with drug and some will not. It is impossible to determine whether "craving" would be completely blocked at this level for each and every neuron. Thus, "chemopreventing" is not enabled. Amendment with "A method of treating craving" would overcome this rejection.

3. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating alcohol craving, does not reasonably provide enablement for a method of treating all forms of craving. The

Art Unit: 1615

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification provides support for treatment of craving alcohol, but does not describe treatment of other forms of craving, such as hunger, nicotine, or opiate. Amendment with a method of treating alcohol craving would overcome this rejection.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claim 6, the phrase "like" in line 1 renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable.

7. Recitation of "non-alcoholic distilled spirit" is confusing. Distilled spirits contain alcohol. The reason an alcoholic liquid is distilled is to refine the alcohol. Therefore, a "non-alcoholic distilled spirit" appears to be a contradiction.

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Chatterjee et al (DE 19847134; hereafter '134).

'134 discloses kava formulations for treating withdrawal of drugs or alcohol.

These formulations are administered in tablets and capsules.

10. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Cody (6,045,825; hereafter '825).

'825 discloses kava formulations for treating nicotine. These formulations are administered in tablets and capsules.

11. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cody (6,045,825; hereafter '825).

'825 discloses kava formulations for treating nicotine. These formulations are administered in tablets and capsules.

12. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Giles, Jr (6,025,363; hereafter '363).

Art Unit: 1615

'363 discloses treatment of hunger craving with a composition comprising kava extract.

13. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bunz (1998).

Bunz discloses non-alcoholic beer compositions comprising kava.

14. Claims 6-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Kavakaze reference (1999).

The Kavakaze reference discloses a carbonated beverage containing kava.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (DE 19847134; hereafter '134) in view of Keenan (5,869,505; hereafter '505) or Cody (6,045,825; hereafter '825) in view of Keenan (5,869,505; hereafter '505) or Giles, Jr (6,025,363; hereafter '363) in view of Keenan (5,869,505; hereafter '505).

'134 teaches kava formulations for treating withdrawal of drugs or alcohol. These formulations are administered in tablets and capsules.

'825 teaches kava formulations for treating nicotine. These formulations are administered in tablets and capsules.

'363 teaches treatment of hunger craving with a composition comprising kava extract.

'505 is relied upon for teaching administration of an active agent by means of a chewing gum to treat nicotine withdrawal.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer kava in a chewing gum formulation to treat drug or alcohol withdrawal, nicotine withdrawal, and hunger cravings with the expectation that kava is effective in treating each of the conditions and the motivation of providing a convenient means of administering the active agent.

17. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al (DE 19847134; hereafter '134) in view of Osborne et al (5,633,008; hereafter '008) or Cody (6,045,825; hereafter '825) in view Osborne et al (5,633,008; hereafter '008) or Giles, Jr (6,025,363; hereafter '363) in view Osborne et al (5,633,008; hereafter '008).

'134 teaches kava formulations for treating withdrawal of drugs or alcohol. These formulations are administered in tablets and capsules.

'825 teaches kava formulations for treating nicotine. These formulations are administered in tablets and capsules.



Art Unit: 1615

'363 teaches treatment of hunger craving with a composition comprising kava extract.

'008 is relied upon for teaching administration of an active agent by means of a transdermal patch to treat nicotine withdrawal.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to administer kava in a transdermal patch formulation to treat drug or alcohol withdrawal, nicotine withdrawal, and hunger cravings with the expectation that kava is effective in treating each of the conditions and the motivation of providing a convenient means of administering the active agent.

18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bunz (1998) or the Kavakaze reference (1999).

Bunz discloses non-alcoholic beer compositions comprising kava. Bunz does not teach non-alcoholic wine compositions.

The Kavakaze reference discloses a carbonated beverage containing kava. The Kavakaze reference does not teach non-alcoholic wine compositions.

While the cited references do not teach non-alcoholic wine kava compositions, in the absence of criticality, it would have been obvious to one skilled in the art at the time of the invention to formulate non-alcoholic wine compositions based upon the teachings of Bunz and The Kavakaze reference, since some people prefer wine to beer.

Art Unit: 1615

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
April 26, 2001

THURMAN K. PAGE  
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